UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,223	11/15/2001	Qingsheng Zhu	279.370US1	8438

7590 06/18/2004

SCHWEGMAN, LUNDBERG,
WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402

EXAMINER	
DROESCH, KRISTEN L	
ART UNIT	**PAPER NUMBER**
3762	7

DATE MAILED: 06/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/001,223	ZHU ET AL.	
	Examiner	Art Unit	
	Kristen L Droesch	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/13/04 (IDS)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11/15/01* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5,6*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-2, 5, 7-11, 13, 16, and 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Boute (6,129,744).

With respect to claim 1, Boute shows a cardiac rhythm management device comprising one or more sensing channels; a controller, wherein the controller is programmed to compute a clinical state vector as a combination of a plurality of parameters related to a patient's heart failure status, including at least one parameter derived from a sense signal and, compare the computed clinical state vector to a previously computed clinical state vector to determine a clinical trajectory indicative of changes in the patient's heart failure status (Col. 3, lines 20-34; Col. 7, line 35 - Col. 8, line 1).

Regarding claim 2, Boute further shows the controller is programmed to deliver paces in accordance with a resynchronization pacing mode (Col. 3, lines 45-47; Col. 5, lines 34-41, Col. 8, lines 14-20).

With respect to claim 5, Boute shows the parameter derived from a sense signal corresponds to a QRS duration in an electrogram (Col. 7, lines 41-44, 62-63; Col. 9, lines 54-58).

Regarding claim 7, Boute shows the controller is programmed to log any changes determined in the patient's heart failure status for later transmission to an external programmer (Col. 7, line 63-Col. 8, line 1).

With respect to claim 8, Boute shows the controller is programmed to compute a clinical trajectory at periodic time intervals (Col. 7, lines 44-51, Col. 8, lines 42-46).

Regarding claim 9, Boute shows a pacing channel for pacing a cardiac site and wherein the controller is further programmed to adjust a pacing parameter if a determined change in the patient's heart failure status exceeds a specified value (Col. 7, line 55-Col. 8, line 24).

With respect to claim 10, Boute shows a plurality of pacing channels, each channel corresponding an electrode for pacing a cardiac site, and wherein the controller is further programmed to switch a pacing site if a determined change in the patient's heart failure status exceeds a specified value (Col. 3, lines 41-56; Col. 5, lines 33-41; Col. 7, lines 55-Col. 8, line 24).

Regarding claim 11, Boute shows a method for delivering pacing therapy to a heart failure patient, comprising operating an implantable cardiac rhythm management device that generates sensing signals from sensed cardiac activity and delivering cardiac pacing therapy through one or more pacing channels to one or more heart chambers, computing a clinical state vector as a combination of a plurality of parameters related to a patient's heart failure status, including at least one parameter derived from a sense signal; and, comparing the computed clinical state vector to a previously computed clinical state vector to determine a clinical trajectory indicative of changes in the patient's heart failure status. (Col. 3, lines 20-34; Col. 7, line 35 - Col. 8, line 1).

With respect to claim 13, Boute shows the computation of the clinical state vector is performed by a controller of the cardiac rhythm management device (Col. 7, lines 30-33).

Regarding claim 16, Boute shows the parameter derived from a sense signal corresponds to a QRS duration in an electrogram (Col. 7, lines 41-44, 62-63; Col. 9, lines 54-58).

With respect to claim 29, Boute shows adjusting a pacing parameter if a determined change in the patient's heart failure status exceeds a specified value (Col. 7, lines 55-Col. 8, line 24).

Regarding claim 30, Boute shows switching a pacing site if a determined change in the patient's heart failure status exceeds a specified value (Col. 3, lines 41-56; Col. 5, lines 33-41; Col. 7, lines 55-Col. 8, line 24).

3. Claims 1, 7-8, 11-13, 20, and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Turcott (6,480,733).

With respect to claim 1, Turcott shows a cardiac rhythm management device comprising one or more sensing channels; a controller, wherein the controller is programmed to compute a clinical state vector as a combination of a plurality of parameters related to a patient's heart failure status, including at least one parameter derived from a sense signal and, compare the computed clinical state vector to a previously computed clinical state vector to determine a clinical trajectory indicative of changes in the patient's heart failure status (Col. 14, lines 8-65; Col. 15, lines 35-62).

Regarding claim 7, Turcott shows the controller is programmed to log any changes determined in the patient's heart failure status for later transmission to an external programmer (Col. 14, lines 29-54).

With respect to claim 8, Turcott shows the controller is programmed to compute a clinical trajectory at periodic time intervals (Col. 14, 18-20).

Regarding claim 11, Turcott shows a method for delivering pacing therapy to a heart failure patient, comprising operating an implantable cardiac rhythm management device that generates sensing signals from sensed cardiac activity and delivering cardiac pacing therapy through one or more pacing channels to one or more heart chambers, computing a clinical state vector as a combination of a plurality of parameters related to a patient's heart failure status, including at least one parameter derived from a sense signal; and, comparing the computed clinical state vector to a previously computed clinical state vector to determine a clinical trajectory indicative of changes in the patient's heart failure status (Col. 14, lines 8-65; Col. 15, lines 35-62).

With respect to claim 12, Turcott shows the computation of the clinical state vector is performed by an external programmer (Col. 14, lines 35-39).

Regarding claim 13, Turcott shows the computation of the clinical state vector is performed by a controller of the cardiac rhythm management device (Col. 14, lines 40-43).

With respect to claim 20, Turcott shows the plurality of parameters includes a measure of heart rate variability (Col. 15, lines 35-62).

Regarding claim 31, Turcott shows the computing a clinical trajectory index CT computed as a sum of the weighted parameters: $CT = \Sigma a_i X_i$ where a weighting factor a_i is assigned to each parameter X_i based upon its clinical significance and the summation is carried out from i = 1 to N, N representing the total number of parameters (Col. 14, lines 60-65).

4. Claims 1, 11-14, and 18, are rejected under 35 U.S.C. 102(e) as being anticipated by Kieval et al. (6,190,324).

With respect to claim 1, Kieval et al. shows a cardiac rhythm management device comprising one or more sensing channels; a controller, wherein the controller is programmed to compute a clinical state vector (HRAC) as a combination of a plurality of parameters related to a patient's heart failure status, including at least one parameter derived from a sense signal and, compare the computed clinical state vector to a previously computed clinical state vector to determine a clinical trajectory indicative of changes in the patient's heart failure status (Figs. 2, 5; Col. 8, line 64-Col. 9, line 50).

Regarding claim 11, Kieval et al. shows a method for delivering pacing therapy to a heart failure patient, comprising operating an implantable cardiac rhythm management device that generates sensing signals from sensed cardiac activity and delivering cardiac pacing therapy through one or more pacing channels to one or more heart chambers, computing a clinical state vector as a combination of a plurality of parameters related to a patient's heart failure status, including at least one parameter derived from a sense signal; and, comparing the computed clinical state vector to a previously computed clinical state vector to determine a clinical trajectory indicative of changes in the patient's heart failure status (Figs. 2, 5; Col. 8, line 64-Col. 9, line 50).

With respect to claim 12, Kieval et al. shows the computation of the clinical state vector is performed by an external programmer (Col. 9, line 66- Col. 10, line 3).

Regarding claim 13, Kieval et al. shows the computation of the clinical state vector is performed by a controller of the cardiac rhythm management device (Col. 9, lines 62-66).

With respect to claim 14, Kieval et al. shows.the clinical state vector is an n-dimensional vector formed from the plurality of clinical parameters where each parameter is mapped to an ordinal scale that represents a coordinate axis in the n-dimensional vector space (Figs. 2, 5).

Regarding claim 18, Kieval et al. shows the plurality of parameters includes a frequency of atrial fibrillation occurrence over a specified period of time (Col. 11, lines 18-22).

5. Claims 1, 3-4, 8, 11, 15, 23, and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Bardy (6,336,903).

With respect to claim 1, Bardy shows a cardiac rhythm management device comprising one or more sensing channels; a controller, wherein the controller is programmed to compute a clinical state vector as a combination of a plurality of parameters related to a patient's heart failure status, including at least one parameter derived from a sense signal and, compare the computed clinical state vector to a previously computed clinical state vector to determine a clinical trajectory indicative of changes in the patient's heart failure status (Figs. 8A-B, Abs. Col. 3, line 17-Col. 5, line 45)

Regarding claim 3, Bardy shows the plurality of parameters includes at least one parameter input by transmission from an external programmer (Col 8, lines 11-50).

With respect to claim 4, Bardy shows the parameter derived from a sense signal corresponds to a PR interval (44) in an electrogram (Fig. 2; Col 7, lines 35-60).

Regarding claim 8, Bardy shows the controller is programmed to compute a clinical trajectory at periodic time intervals (Col. 8, lines 51-54).

With respect to claim 11, Bardy shows a method for delivering pacing therapy to a heart failure patient, comprising operating an implantable cardiac rhythm management device that

generates sensing signals from sensed cardiac activity and delivering cardiac pacing therapy through one or more pacing channels to one or more heart chambers, computing a clinical state vector as a combination of a plurality of parameters related to a patient's heart failure status, including at least one parameter derived from a sense signal; and, comparing the computed clinical state vector to a previously computed clinical state vector to determine a clinical trajectory indicative of changes in the patient's heart failure status (Figs. 8A-B; Abs.; Col. 3, line 17-Col. 5, line 45).

Regarding claim 15, Bardy shows the parameter derived from a sense signal corresponds to a PR interval in an electrogram (Fig. 2; Col 7, lines 35-60).

With respect to claim 23, Bardy shows the plurality of parameters includes a measured or derived left ventricular end diastolic pressure (Col. 15, lines 20-32).

Regarding claim 31, Bardy shows the computing a clinical trajectory index CT computed as a sum of the weighted parameters: $CT = \Sigma a_i X_i$ where a weighting factor a_i is assigned to each parameter X_i based upon its clinical significance and the summation is carried out from $i = 1$ to N, N representing the total number of parameters (Col. 18, lines 27-38).

6. Claims 1, 11, 13, 23-24, and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Tchou et al. (2001/0037067).

With respect to claim 1, Tchou et al. shows a cardiac rhythm management device comprising one or more sensing channels; a controller, wherein the controller is programmed to compute a clinical state vector as a combination of a plurality of parameters related to a patient's heart failure status, including at least one parameter derived from a sense signal and, compare the computed clinical state vector to a previously computed clinical state vector to determine a

clinical trajectory indicative of changes in the patient's heart failure status (Page 2, Paras. 013-018).

With respect to claim 11, Tchou et al. shows a method for delivering pacing therapy to a heart failure patient, comprising operating an implantable cardiac rhythm management device that generates sensing signals from sensed cardiac activity and delivering cardiac pacing therapy through one or more pacing channels to one or more heart chambers, computing a clinical state vector as a combination of a plurality of parameters related to a patient's heart failure status, including at least one parameter derived from a sense signal; and, comparing the computed clinical state vector to a previously computed clinical state vector to determine a clinical trajectory indicative of changes in the patient's heart failure status (Page 2, Paras. 013-018).

With respect to claims 23-24, Tchou et al. shows the plurality of parameters includes a measured or derived left ventricular end diastolic pressure or includes a measured or derived systolic pressure index. (Page 5, Para. 0050).

Regarding claim 28, Tchou et al. shows the plurality of parameters includes a ratio of minute ventilation to activity level (Page 8, Para. 0083, Fig. 4).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 6 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over or Turcott (6,480,733), or Kieval et al. (6,190,324) or Bardy (6,336,903) or Tchou et al.

(2001/0037067) in view of VanHout (6,668,194). Although Boute, Turcott, Kieval et al., Bardy and Tchou each fail to teach the parameter derived from a sense signal corresponds to an inter-ventricular delay between senses in the right and left ventricles, attention is directed to VanHout which teaches that monitoring of heart failure can be based on an inter-ventricular delay between senses in the right and left ventricles. Therefore it would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to utilize pulse pressure as one of the plurality of parameters, since VanHout teaches that it is well known in the art to monitor heart failure status based an inter-ventricular delay between senses in the right and left ventricles.

9. Claims 19, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turcott (6,480,733), or Kieval et al. (6,190,324) or Bardy (6,336,903) or Tchou et al. (2001/0037067). Boute, Turcott, Kieval et al., Bardy and Tchou each disclose the claimed invention except for the plurality of parameters including the frequency at which ventricular tachycardia converts to ventricular fibrillation over a specified period of time or the frequency of ectopic beats over a specified period of time. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the plurality of parameters as taught by Boute, Turcott, Kieval et al., Bardy and Tchou with the frequency at which ventricular tachycardia converts to ventricular fibrillation over a specified period of time or the frequency of ectopic beats over a specified period of time, since applicant has not disclosed that these particular parameters provide any criticality and /or unexpected results and it appears that the invention would perform equally well with any of the plurality of parameters such as the assorted parameters taught Boute, Turcott, Kieval et al., Bardy and Tchou for indicating heart failure.

10. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy (6,336,903). Bardy discloses the claimed invention except for the plurality of parameters including a measured body weight of the patient. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the plurality of parameters as taught by Bardy with the measured body weight of the patient, since applicant has not disclosed that this particular parameter provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any of the plurality of parameters such as the assorted parameters taught Bardy for indicating heart failure.

11. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Turcott (6,480,733), or Kieval et al. (6,190,324) or Bardy (6,336,903) or Tchou et al. (2001/0037067) in view of Sun et al. (6,668,188). Although Boute, Turcott, Kieval et al., Bardy and Tchou each fail to teach the plurality of parameters includes an average of the patient's exertion level over a specified period of time, attention is directed to Sun et al. which teaches that monitoring of heart failure can be based on an average of the patient's exertion level over a specified period of time. Therefore it would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to utilize pulse pressure as one of the plurality of parameters, since Sun et al. teaches that it is well known in the art to monitor heart failure status based on an average of the patient's exertion level over a specified period of time.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the

inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

12. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boute (6,129,744), or Turcott (6,480,733), or Kieval et al. (6,190,324) or Bardy (6,336,903) or Tchou et al. (2001/0037067) in view of Turcott (6,575,912). Although Boute, Turcott, Kieval et al., Bardy and Tchou each fail to teach the plurality of parameters includes a measured or derived pulse pressure index, attention is directed to Turcott which teaches that heart failure status can be determined based on pulse pressure. Therefore it would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to utilize pulse pressure as one of the plurality of parameters, since Turcott teaches that it is well known in the art to monitor heart failure status can be determined based on pulse pressure.

13. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boute (6,129,744), or Turcott (6,480,733), or Kieval et al. (6,190,324) or Bardy (6,336,903) or Tchou

et al. (2001/0037067) in view of Brockway et al. (6,575,912). Although Boute, Turcott, Kieval et al., Bardy and Tchou each fail to teach to teach the plurality of parameters includes a measured or derived maximum left ventricular dp/dt index, attention is directed to Brockway et al. which teaches that heart function status can be determined based on maximum left ventricular dp/dt index (Col. 1, line 39-Col. 2, line 6). Therefore it would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to utilize pulse pressure as one of the plurality of parameters, since Brockway et al. teaches that it is well known in the art to monitor heart function based on maximum left ventricular dp/dt index.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Warkentin (2003/0004548) shows a system that measures QRS duration to monitor CHF. Kroll (6,645,153) shows a CHF monitoring system. Park et al. (6,741,885) shows a CHF monitoring system utilizing activity and respiration parameters. Porat et al. (6,277,078) shows left ventricular pressure sensors.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L Droesch whose telephone number is 703-605-1185. The examiner can normally be reached on M-F, 10:00 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kristen Driscoll

Angela D Sykes

kld

ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700